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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,840	01/02/2002	Gail Lewandowski	08593.0001	4383
22852	7590	06/16/2004	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			ANGELL, JON E	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

34.

## Office Action Summary

Application No.

09/914,840

Applicant(s)

LEWANDOWSKI ET AL.

Examiner

J. Eric Angell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-87 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### DETAILED ACTION

Claims 1-87 are currently pending in the application and are addressed herein.

#### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-21, drawn to an *in situ* method for packaging DNA into a viral particle and treating a viral infection comprising applying at least one unpackaged DNA construct to the site of an active viral infection in an organism, wherein at least one applied DNA construct is packaged into viral particles.

Group II, claim(s) 22-48, drawn to a method of treating a viral infection comprising the steps of: 1) applying a composition comprising one or more unpackaged amplicons to a site of viral infection in an organism, wherein one or more of the amplicons encode at least one anti-viral compound, and 2) expressing at least one of the encoded anti-viral compound in the organism.

Group III, claim(s) 49-61, drawn to a composition comprising one or more amplicons capable of directing the inducible expression of at least one anti-viral compound in neuronal cells.

Group IV, claim(s) 62-65, drawn to a method of reducing the frequency or severity of HSV recurrences in an organism comprising administering the composition of claim 49.

Group V, claim(s) 66-81, drawn to a composition for treating HSV infections comprising one or more amplicons programmed to express: 1) at least one anti-viral compound in HSV infected epithelial cells, and 2) at least one anti-viral compound in HSV infected neuronal cells, wherein amplicon-directed expression of at least one anti-viral compound in HSV neuronal cells is inducible.

Group VI, claim(s) 82-87, drawn to a method for treating HSV infection comprising administering the composition of claim 66 to an organism.

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2. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: In order for the claims to have unity of invention, there must be a technical relationship among those inventions involving one or more of the same or corresponding special technical features. In the instant case, the claims are drawn to compositions as well as methods which utilize the compositions.

3. The invention that is Group I are claims that are linked by the special technical feature that is a method comprising applying at least one unpackaged DNA construct to the site of an active viral infection in an organism, wherein at least one applied DNA construct is packaged into viral particles. There is no special technical feature that links this Group to any of the other Groups as each of the other Groups require different composition, have different method steps and/or have different results.

4. For instance, Group II is drawn to claims that are linked by a method of treating a viral infection comprising the steps of: 1) applying a composition comprising one or more unpackaged amplicons to a site of viral infection in an organism, wherein one or more of the amplicons encode at least one anti-viral compound, and 2) expressing at least one of the encoded anti-viral compound in the organism. Here, the amplicon encoding at least one anti-viral gene is not required for Group I.

5. Group III is drawn to claims that are linked by a composition comprising one or more amplicons capable of directing the inducible expression of at least one anti-viral compound in neuronal cells and Group IV is drawn to claims that are linked by a method of reducing the frequency or severity of HSV recurrences in an organism comprising administering the composition of Group III. Here Groups II, III and IV are linked by a technical feature that is an amplicon capable of directing the inducible expression of at least one anti-viral compound in neuronal cells (i.e. claim 49). However, this technical feature is not novel (as indicated by the "X" reference in the International search report). In order for a technical feature to be considered a special technical feature it must be novel. Therefore, there is no unity of invention between Groups II, III and IV. Furthermore, these Groups also do not share a special technical feature with the other Inventions (Groups I, II, V and VI).

6. Group V is drawn to claims that are linked by a composition for treating HSV infections comprising one or more amplicons programmed to express: 1) at least one anti-viral compound in HSV infected epithelial cells, and 2) at least one anti-viral compound in HSV infected neuronal cells and Group VI is drawn claims linked by a method for treating HSV infection comprising administering the composition of Group V to an organism. Therefore Groups V and VI are linked by a technical feature that is one or more amplicons programmed to express: 1) at least one anti-viral compound in HSV infected epithelial cells, and 2) at least one anti-viral compound in HSV infected neuronal cells. However, since this technical feature is not novel (as evidenced by the "X" reference cited in the ISR) there is no special technical feature linking the Groups. Furthermore, there is no special technical feature linking these Groups (V and VI) to the other Groups (I-IV).

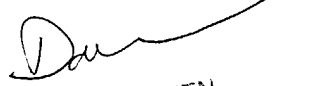
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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (571) 272-0756. The examiner can normally be reached on M-F (8:00-5:30) with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

  
DAVE T. NGUYEN  
PRIMARY EXAMINER

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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